REMARKS/ARGUMENTS

Receipt of the Office Action mailed May 29, 2002 is acknowledged. Claims 1- 4 remain in this application. Claims 5-17 have been canceled without prejudice or disclaimer. Claim 1 has been amended. Support for the amendment to claim 1 can be found throughout the original disclosure. No new matter has been entered.

Objection to the Drawings

Enclosed herewith under a separate letter to the PTO draftsperson are formal drawings to replace the informal drawings originally filed with the application. Applicants erroneously believed that formal drawings were previously filed with the application, thus the cause of the confusion regarding the Figure 2B provided by applicant in the last response and the Figure 2B included in the outstanding Office Action. Applicants regret any inconvenience this may have caused the Examiner. Also enclosed is a marked up copy, in red, of Figure 2B showing placement of reference number 175.

Section 112, First Paragraph Rejection

In paragraph 3 of the Office Action, claims 1- 4 stand rejected under 35 U.S.C. 112, first paragraph as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Reconsideration and withdrawal of the rejections are respectfully requested.

The Examiner argues there is no support in the original disclosure for detecting failures that can result from *multiple failure modes*. The Examiner takes the position that the original disclosure provides support for multiple detection schemes for the same failure, referring to the

instant specification at page 7, lines 22-29 for support. The original disclosure provides support for both multiple detecting schemes as asserted by the Examiner and for multiple failure modes as set forth in the claims. Indeed, the claims as originally filed provide support for multiple failure modes, e.g., the fluid metering failure of claim 5 and sample dilution failures of claim 10. Also, page 26, line 8 of the specification recites "several failure modes...." Thus, applicants respectfully submit that there is sufficient support and written description under section 112, first paragraph.

a single failure mode

Section 112, Second Paragraph Rejection

In paragraph 5 of the Office Action, claims 1-4 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite for recital of the term "can" in the claims. Reconsideration and withdrawal of the rejections are respectfully requested. Applicants submit that there is nothing improper, *per se*, with the use of a conditional term such as "can." Applicants submit that the use of "can" in the claims is analogous to the use of "optionally" (i.e., an alternative expression), which has been held to satisfy section 112, second paragraph. *See* MPEP 2173.05(h) II. Accordingly, applicants submit that claims 1 to 4 satisfy section 112, second paragraph.

Section 101 Rejection

In paragraph 7 of the Office Action, claims 1-4 stand rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter. Reconsideration and withdrawal of the rejection are respectfully requested. Applicants disagree with the Examiner's assessment that the claims are directed to manipulation of an abstract or ideal. Applicants submit that the claims fall within the safe harbor provisions of MPEP 2106(IV)B2(b)ii) ("Computer Related Process Limited to a Practical Application in the Technological Arts"). In this instance the process is limited to an

application in the art of an analyzer for conducting clinical assays. Accordingly, applicants submit that claims 1 to 4 satisfy section 101.

Section 102(b) rejections

In paragraphs 9 and 10 of the Office Action, claims 1-4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hoth et al., U.S. Patent No. 5,710,723 ("Hoth") or Farmer, U.S. Patent No. 5,315,529 ("Farmer"). In view of the foregoing amendments and the remarks that follow, reconsideration and withdrawal of the rejections are respectfully requested.

With regard to Hoth, claim 1 has been amended to recite in the body of the claim "an analyzer for conducting clinical assays." The material, i.e., apparatus, acted upon in a method claim must be given patentable weight. *See* MPEP 2116. As applicants pointed out in their previous reply, Hoth is directed to operation of industrial equipment, not an analyzer for conducting clinical assays as claimed. Nothing in Hoth would lead one skilled in the art to adapt the teachings of Hoth to an analyzer for conducting clinical assays. Accordingly, Hoth fails to anticipate or render obvious the claimed invention.

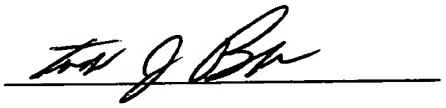
With regard to Farmer, the claims have been amended to recite the multiple failure modes within the body of the claim. Thus, the arguments set forth in applicants' previous reply, namely, that errors that can result from assay failures that are not leaks (e.g., such as dilution errors) cannot be determined because there are no events that are detected other than leaks, is fully applicable in this instance. See page 6 of the reply submitted February 27, 2002.

Based on the foregoing, applicants believe the application is now in condition for allowance. Favorable reconsideration and notice of allowance are solicited. If any questions arise which can

be disposed through interview, the Examiner is encouraged to contact Applicants' attorney at the telephone number listed below.

Please charge any fees which may be required for this submission to Johnson & Johnson Deposit Account No. 10-0750/CDS-215/TFV.

Respectfully submitted,



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Dated: August 29, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

2. (Twice Amended) A method for detecting failures that can result from multiple failure modes in an analyzer for conducting clinical assays comprising:

a) providing an analyzer for conduction clinical assays that can have multiple failure modes,

b) [a)] identifying potential errors that can result in assay failures in [an] the analyzer

c) [b)] identifying potential sources of the potential errors identified in [a)] b),

d) [c)] determining the probability that an error source so identified will result in a clinically significant error,

e) [d)] identifying potential error detection measures corresponding to the source of potential errors,

f) [e)] selecting and implementing multiple error detection measures for each failure mode based on their probability of reducing errors to an acceptable limit along with a low probability of the false detection of an assay failure.